



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/802,314	03/17/2004	Van Le Huynh	ECV-5539CON	3894

7590 01/06/2009
EDWARDS LIFESCIENCES LLC
One Edwards Way
Irvine, CA 92614

EXAMINER

PELLEGRINO, BRIAN E

ART UNIT	PAPER NUMBER
----------	--------------

3738

MAIL DATE	DELIVERY MODE
-----------	---------------

01/06/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/802,314
Filing Date: March 17, 2004
Appellant(s): HUYNH ET AL.

Rajiv Yadav
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 9/22/08 appealing from the Office action mailed 3/20/08.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

WITHDRAWN REJECTIONS

The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the examiner. Claims 1-7,11-18 rejected over Vanney (5843179) is not being presented to the Board for review.

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct for claims 1-8,11-19 rejected over Totten under 35 U.S.C. 102 and claims 9,10,20,21 under 35 U.S.C. 103 over Totten with Huynh and Reichart.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

4,477,930	Totten	10-1984
4,626,255	Reichart et al.	12-1986
5,928,281	Huynh et al.	7-1999

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-8,11-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Totten et al. (4477930). Totten et al. disclose a tubular fabric with a stent frame and a ring insert, see Figs. 1, 6, 7, and col. 4, lines 8-11. Claims in a pending application should be given their broadest reasonable interpretation, *In re Hyatt*, 54 USPQ 2d 1664 (Fed. Cir. 2000). Therefore, the Totten suture ring is configured to pivot or move between two positions since it is made of an elastomer, col. 4, lines 12,13, and Fig. 8, which illustrates that the sewing ring can pivot about the edge. Totten discloses the sewing ring to be pliable or suture permeable (col. 4, line 16), thus it can be interpreted to be bi-stable because of its flexibility and placement at a seam or edge as seen in Fig. 8 and since it will not deform permanently, it is stable when it moves. Additionally, since it is flexible it can be interpreted that it is stable and will not break. The ring can be considered “**generally** frusto-conical” as seen in Figs. 7,10. Totten also discloses the

fabric covers the ring and connects the ring to the stent periphery at a seam, col. 5, lines 12-17. Fig. 8 also shows the insert ring to be “substantially” planar.

Claims 9 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Totten '930 in view of Huynh et al. (5928281). Totten is explained supra. However, Totten does not disclose alternating thick and thin regions in the insert ring. Huynh teaches (Figs. 27, 32) that an insert ring for a suture ring is provided with thick and thin regions. It would have been obvious to one of ordinary skill in the art to use thick and thin regions as taught by Huynh in the sewing ring of Totten such that it provides more stability in maintaining the fabric covering to the ring.

Claims 10,21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Totten '930 in view of Reichart et al. (4626255). Totten is explained supra. However, Totten does not disclose the insert ring with a radially undulating shape. Reichart et al. teach (Fig. 1) that the sewing ring has an undulating shape. It would have been obvious to one of ordinary skill in the art to use the undulating shape for the sewing ring as taught by Reichart with the heart valve of Totten in order to more closely match the shape of the natural annulus to where the prosthetic valve is being implanted.

(10) Response to Argument

Appellant mentions on page 4 of the Brief submitted on 9/22/08 that bi-stable means an element is moveable between two positions. It is the examiner's position because of the structural design of Totten's sewing ring being placed at an edge and is pliable or flexible it is fully capable of moving between two positions about the edge. As

Art Unit: 3738

a result this would be bi-stable according to Appellant's definition of bi-stable. The examiner is entitled to give terms in a claim its plain meaning as interpreted by one of ordinary skill in the art. It is noted that the specification must clearly set forth the definition of a term explicitly and with reasonable clarity, deliberateness, and precision. Exemplification is not an explicit definition. Even explicit definitions can be subject to varying interpretations. See *Teleflex, Inc. v. Ficosa North America Corp.*, 63 USPQ2d 1374, 1381 (Fed. Cir. 2002), *Rexnord Corp. v. Laitram Corp.*, 60 USPQ2d 1851, 1854 (Fed. Cir. 2001) and MPEP 2111.01. In addition Appellant states the examiner improperly interprets claim language such as the capability of moving or pivoting from a first position to a second position alleging the examiner gives no weight to the ability to move. This is an incorrect assessment of the examiner's rejection since the examiner clearly establishes how or why the Totten sewing ring is capable of pivoting as described above. It appears Appellant has not followed the examiner's rejection and understood that the term "stable" is a word that describes a condition of an element, but without any comparative measures it has no special meaning. This term has many meanings, i.e. 1) not subject to change 2) does not deteriorate. In considering these general or common definitions it clearly can be said that the pliability of Totten's sewing ring allows for the ring to move without deforming or changing permanently since it is flexible. Additionally since the ring is not made of a degradable material it clearly does not deteriorate. Thus, since the ring moves or pivots the sewing ring can be said to go from one position to another and maintains a stable condition since it will not change or even deteriorate. As a result it can be said that the Totten sewing ring then has two bi-

stable positions. The Appellant argues that insufficient weight has been given to the terminology of the claims. This is incorrect. The examiner has merely explained that the sewing ring moves between two positions, but since the claims and specification fail to establish what defines a "stable" position, the broadest interpretation is given to the terms. Applicant fails to present any comments as to whether a material property or structural feature imparts the bi-stability to the claimed sewing ring. Thus, one would look to the specification. The specification states on page 16 that the two positions define "bi-stability". So since such a structure is described to just have the ability to move between two positions, it is bi-stable. Therefore, since Totten's sewing ring can pivot between two positions it is bi-stable and anticipates the claims.

In response to appellant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the appellant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Thus, the rejection over Totten and Huynh is maintained.

In response to appellant's argument that there is no suggestion to combine the Totten reference with Reichart, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so

Art Unit: 3738

found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it is well known in the prosthetic art that when implanting prostheses, the surgeon often matches a prosthetic surface with the contour of the bone, tissue or organ structure in which the implant is to replace or assist. Common sense would lead a surgeon to match the structures and not have non-congruent structures. A square is not matched up with a triangle, thus one of ordinary skill clearly would look to Reichart to form the sewing ring of Totten with an undulating shape to match the annulus of the heart valve since this is the normal contour around the heart valve.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Brian E Pellegrino/
Primary examiner, Art Unit 3738

Conferees:

/Corrine McDermott/
SPE, Art Unit 3738

/Thomas Barrett/
TQAS TC3700

Application/Control Number: 10/802,314
Art Unit: 3738

Page 8